

## SHORT REPORT

# Research in emergency situations: with or without relatives consent

The CRASH Trial Management Group

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Patients in emergency situations with impaired consciousness are unable to give informed consent to participate in clinical trials. In this situation, some ethics committees ask that consent is obtained from a relative or a legal representative. Others however, waive the need for informed consent and allow the doctor in charge to take responsibility for entering such patients. This study used data from the MRC CRASH Trial, an international randomised controlled trial of corticosteroids in head injury, to assess whether the practice of waiving consent results in earlier administration of the trial treatment. It was found that time from injury to randomisation was significantly reduced (1.2 hours, 95% CI 0.7 to 1.8 hours) and patient recruitment was higher in hospitals where consent was waived compared with those that required relatives consent.

Patients with life and death emergencies such as those with head injuries and impaired consciousness are unable to give informed consent to participation in clinical trials. Nevertheless, controlled clinical trials are essential in such situations to identify effective ways to prevent death and long term disability. In 1995 the US Food and Drug Administration changed its rules to permit research in emergency care without the need for informed consent and many ethics committees now allow consent to be waived in medical emergencies involving unconscious patients.<sup>1,2</sup> Others however, require that consent is obtained from a relative or a legal representative of the person not able to consent to trial entry.

In many acute neurological emergencies it is essential that treatment is given as soon as possible. For example, after acute central nervous system trauma axonal disruption continues for several hours and there may be an early phase when neurological deficit is reversible.<sup>3</sup> The MRC CRASH trial is an international multicentre randomised controlled trial among adults with head injuries and impaired consciousness of the effects of a short term corticosteroid infusion on death and disability.<sup>4</sup> Every effort is made to ensure that the trial treatment is given as soon as possible after the head injury and only patients who are within eight hours of injury are eligible for inclusion.

## DATA ANALYSIS

Currently there are 116 hospitals in 40 countries taking part in the CRASH Trial and 4000 patients have been randomised. In 78 hospitals, the relevant ethics committee has agreed to waive the need for consent, while in 38 hospitals, the committee requires that consent is obtained from a relative. To assess whether the practice of waiving consent results in earlier administration of the trial treatment and increased trial recruitment, we compared the average time from injury to randomisation and average number of patients recruited per month in the two groups of hospitals. In the MRC CRASH trial, time since injury is one of the inclusion criteria and so

information on this variable is recorded for all randomised patients. For each participating hospital the average time to randomisation was estimated and the average of these hospital averages was estimated for hospitals that waive consent and those that do not.

## RESULTS

There was a significant difference in the mean time to randomisation between hospitals that waived consent and those that required the consent of a relative ( $p < 0.0001$ ). In hospitals that waived consent, the average time from injury to randomisation was 3.2 hours (SE = 0.16). Among those that required relatives consent the corresponding figure was 4.4 hours (SE = 0.21). The difference in the mean time to randomisation was 1.2 hours (95% CI 0.7 to 1.8 hours). Among hospitals that waived consent, the average number of patients recruited per month was 2.0 patients (SE = 0.29). Among those that required relatives consent the corresponding figure was 1.5 patients (SE = 0.24). The difference in the average monthly recruitment was 0.51 (−0.36 to 1.39).

## DISCUSSION

Although the time from injury to randomisation is significantly reduced in hospitals that waived consent, we cannot exclude the possibility that there are other factors that account for the difference, such as the provision of rapid emergency transport to hospital. On the other hand, given that many patients admitted to hospital after head injury are unaccompanied, it is inevitable that the need to obtain consent from relatives will entail some delay to trial enrolment and the start of the trial treatment.

Waiving the need for consent for patients in emergency situations with impaired consciousness means that patients can be treated sooner and this may increase their potential to benefit from the new treatment. If, as in the CRASH trial, patients must be enrolled within a specified time period, waiving consent would also increase the numbers of patients that are enrolled in controlled trials, which would facilitate the identification of safer and more effective treatments for patients in life threatening emergencies.

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